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REMARKS

Applicants respectfully request consideration of this application as amended herein. The Examiner has required that Applicants designate one of the inventions that belong to the two identified set of claims as set forth in the Office Action (03/29/02, page 2), and then elect to prosecute one of those two groups of claims. Applicants respectfully confirm the election of Group I, Claims 11-26 and 39-56 for prosecution. Accordingly, claims 27-38 are withdrawn from further consideration.

Claims 40 – 50 and 52 – 56 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action states it is unclear whether the Applicants are claiming a "mandrel" or "catheter" in the dependent claims corresponding to independent claims 39, 45, and 51 (Office Action, 03/29/02, page 3). Independent claims 39, 45, and 51 have been amended to claim an "apparatus," with the corresponding dependent claims also claiming an "apparatus." As such, Applicants respectfully submit the rejection under 35 U.S.C. § 112, second paragraph has been overcome and request removal of the rejection.

Claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 have been rejected under 35 U.S. C. § 102(b) as being anticipated by Shank, et al. (U.S. Patent No. 5,147,317, hereinafter "Shank"). Claim 12 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Hibbs, et al. (U.S. Patent No. 4,950,257, hereinafter "Hibbs"). Claims 11-26 and 39-56 have been rejected under § 103(a) as being unpatentable over Kraus, et al. (U.S. Patent No. 5,246,420, hereinafter "Kraus"), in view of Lorenzo (U.S. Patent No. 5,836,892, hereinafter "Lorenzo").

Claims 39 – 56 have been amended. No new matter has been added by the amendments. No new claims have been added. No claims have been canceled. As such, claims 11 – 26 and 39 – 56 remain pending in this application.

Claims 11, 13, 16 – 18, 39, 42 – 45, 48 – 51, and 54 – 56 have been rejected under 35 U.S.C. § 102(b) as being unpatentable over Shank. Independent claim 11 provides:

> A catheter comprising:
>
> a mandrel comprised of a variable stiffness, non-metal material, said mandrel uniformly tapered from a proximal section to a distal section, and said mandrel adapted to reinforce said catheter. (emphasis added)

Shank discloses a guidewire for use in the placement of a catheter. The guidewire includes an elongate flexible core wire and a helical coil wrapped about the core wire. (Shank, col. 4, lines 20 – 40, and Figure 1). The guidewire disclosed in Shank is intended to reduce the contact between the guidewire and the inner surface of a catheter to lessen resistance of guidewire movement within the catheter lumen as the catheter is advanced over the guidewire. (Shank, col. 7, lines 23 – 27). Nothing in Shank discloses a mandrel adapted to reinforce a catheter.

In contrast, claim 11 provides a "mandrel adapted to reinforce said catheter." A mandrel is not equivalent to a guidewire. Functionally, whereas a mandrel is part of a catheter and moves with the catheter, a guidewire is independent of the catheter and does not move with the catheter. Thus, there is normally no movement of the mandrel relative to the rest of the catheter, whereas a guidewire does move relative to the catheter. Moreover, a guidewire serves as an aid in the placement of a catheter in a selected site within a human body. A mandrel, as claimed, is adapted to reinforce a catheter. As such, Applicants respectfully submit that claim 11 is not anticipated by Shank under 35 U.S.C.

§ 102(b), and request withdrawal of the rejection the claim. Claims 13 and 16 – 18 depend either directly or indirectly from independent claim 11, and thus include the limitation of a "mandrel adapted to reinforce said catheter." As such, Applicants respectfully submits that claims 13 and 16 – 18 are also not anticipated Shank under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

Independent claim 39 provides:

> An apparatus for reinforcing a catheter for insertion into a body lumen comprising:
>
> a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by necking at high temperatures such that said proximal section is stiffer than said distal section. (emphasis added)

Shank discloses a guidewire for use in the placement of a catheter. The guidewire includes an elongate flexible core wire and a helical coil wrapped about the core wire. (Shank, col. 4, lines 20 – 40, and Figure 1). The guidewire disclosed in Shank is intended to reduce the contact between the guidewire and the inner surface of a catheter to lessen resistance of guidewire movement within the catheter lumen as the catheter is advanced over the guidewire. (Shank, col. 7, lines 23 – 27). Nothing in Shank discloses a mandrel for reinforcing a catheter.

In contrast, claim 39 provides a "mandrel for reinforcing said catheter." A mandrel is not equivalent to a guidewire. Functionally, whereas a mandrel is part of a catheter and moves with the catheter, a guidewire is independent of the catheter and does not move with the catheter. Thus, there is normally no movement of the mandrel relative to the rest of the catheter, whereas a guidewire does move relative to the catheter.

Moreover, a guidewire serves as an aid in the placement of a catheter in a selected site within a human body. A mandrel, as claimed, is adapted to reinforce a catheter. As such, Applicants respectfully submit that claim 39 is not anticipated by Shank under 35 U.S.C. § 102(b), and request withdrawal of the rejection the claim. Claims 42 – 44 depend either directly or indirectly from independent claim 39, and thus include the limitation of a "mandrel for reinforcing said catheter." As such, Applicants respectfully submits that claims 42 – 44 are also not anticipated Shank under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

Independent claim 45 provides:

> An apparatus for reinforcing a catheter for insertion into a body lumen comprising:
>
> a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section. (emphasis added)

Shank discloses a guidewire for use in the placement of a catheter. The guidewire includes an elongate flexible core wire and a helical coil wrapped about the core wire. (Shank, col. 4, lines 20 – 40, and Figure 1). The guidewire disclosed in Shank is intended to reduce the contact between the guidewire and the inner surface of a catheter to lessen resistance of guidewire movement within the catheter lumen as the catheter is advanced over the guidewire. (Shank, col. 7, lines 23 – 27). Nothing in Shank discloses a mandrel for reinforcing a catheter.

In contrast, claim 45 provides a "mandrel for reinforcing said catheter." A mandrel is not equivalent to a guidewire. Functionally, whereas a mandrel is part of a

catheter and moves with the catheter, a guidewire is independent of the catheter and does not move with the catheter. Thus, there is normally no movement of the mandrel relative to the rest of the catheter, whereas a guidewire does move relative to the catheter. Moreover, a guidewire serves as an aid in the placement of a catheter in a selected site within a human body. A mandrel, as claimed, is adapted to reinforce a catheter. As such, Applicants respectfully submit that claim 45 is not anticipated by Shank under 35 U.S.C. § 102(b), and request withdrawal of the rejection the claim. Claims 48 – 50 depend either directly or indirectly from independent claim 45, and thus include the limitation of a "mandrel for reinforcing said catheter." As such, Applicants respectfully submits that claims 48 – 50 are also not anticipated Shank under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

Independent claim 51 provides:

> An apparatus for reinforcing a catheter for insertion into a body lumen comprising:
>
> a non-metal material <u>mandrel for reinforcing said catheter</u> comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by taper extruding such that said proximal section is stiffer than said distal section. (emphasis added)

Shank discloses a guidewire for use in the placement of a catheter. The guidewire includes an elongate flexible core wire and a helical coil wrapped about the core wire. (Shank, col. 4, lines 20 – 40, and Figure 1). The guidewire disclosed in Shank is intended to reduce the contact between the guidewire and the inner surface of a catheter to lessen resistance of guidewire movement within the catheter lumen as the catheter is advanced

over the guidewire. (Shank, col. 7, lines 23 – 27). Nothing in Shank discloses a mandrel for reinforcing a catheter.

In contrast, claim 51 provides a "mandrel for reinforcing said catheter." A mandrel is not equivalent to a guidewire. Functionally, whereas a mandrel is part of a catheter and moves with the catheter, a guidewire is independent of the catheter and does not move with the catheter. Thus, there is normally no movement of the mandrel relative to the rest of the catheter, whereas a guidewire does move relative to the catheter. Moreover, a guidewire serves as an aid in the placement of a catheter in a selected site within a human body. A mandrel, as claimed, is adapted to reinforce a catheter. As such, Applicants respectfully submit that claim 51 is not anticipated by Shank under 35 U.S.C. § 102(b), and request withdrawal of the rejection the claim. Claims 54 – 56 depend either directly or indirectly from independent claim 45, and thus include the limitation of a "mandrel for reinforcing said catheter." As such, Applicants respectfully submits that claims 54 – 56 are also not anticipated Shank under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

Claim 12 has been rejected under 35 U.S.C. § 102(b) as being unpatentable over Hibbs. Hibbs discloses a sheath that provides a sealed and protected pathway for a catheter into a blood vessel. (Hibbs, col. 3, lines 50 – 60, and Figures 1 & 2). Nothing in Hibbs discloses a mandrel adapted to reinforce a catheter.

Claim 12 depends from independent claim 11 and thus includes the limitation of a "mandrel adapted to reinforce said catheter." A mandrel is not equivalent to a sheath as disclosed in Hibbs. Functionally, whereas a mandrel is part of a catheter and moves with the catheter, a sheath is independent of the catheter and does not move with the catheter.

Moreover, a sheath serves as an aid in the placement of a catheter in a selected site within a human body. A mandrel, as claimed, is adapted to reinforce a catheter. As such, Applicants respectfully submit that claim 12 is not anticipated by Hibbs under 35 U.S.C. § 102(b), and request withdrawal of the rejection the claim.

Claims 11 – 26 and 39 – 56 have been rejected under 35 U.S.C. § 103(b) as being unpatentable over Kraus in view of Lorenzo. Independent claims 11, 19, 39, and 45 all include the limitation of a non-metal material mandrel. Claims 12 – 18, 20 – 26, 40 – 44, and 46 – 56 are dependent claims and thus include the limitation of a non-metal material mandrel. Kraus discloses a catheter that includes a balloon 10, a guidewire with a tapered mandrel 11, an outer catheter shaft of tube 14, and a proximal adapter 15. The distal end of the guidewire passes through two tubular elements 21, 22 inside the outer catheter tube 14 and the balloon 10 and terminates in a tip coil 12 emerging from the catheter end. The tubular elements provide column support for the balloon. (Klaus, col. 7, lines 54 – 62, and Figure 1). Nothing in Kraus discloses a mandrel made of non-metal material.

Lorenzo discloses a guidewire a tip section of a guidewire 12 having radiopaque markers 14. The radiopaque markers are spaced apart by polyimide tubing segments 31 – 37 mounted on a stainless steel core wire 40. (Lorenzo, col. 2, lines 20 – 30, and Figure 1). Nothing in Lorenzo teaches or suggests a mandrel made of non-metal material, and as such, Lorenzo fails to cure the deficiency of Kraus.

It is respectfully submitted that Kraus and Lorenzo do not teach or suggest a combination with each other. It would be impermissible hindsight, based on Applicants' own disclosure, to combine Kraus and Lorenzo.

Applicants respectfully submit that there is no motivation to combine Kraus with Lorenzo. The Office Action states that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to form the Kraus mandrel from polyimide material, as taught by Lorenzo, as known material used to form mandrels." (Office Action, 03/29/02, page 7). Here, the Office Action merely states an advantage of substituting the guidewire (i.e., a guidewire with tubing segments) of Lorenzo, with the guidewire Kraus, without explaining what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.

Even if Kraus and Lorezo were combined, it would still not result in the limitations of claims 11, 19, 39, and 45. Combining the guidewire from Lorenzo with the catheter of Kraus would not result in a non-metal material mandrel. Moreover, the guidewire would not function as a mandrel, because the Lorenzo guidewire merely provides a tip section with highly visible radiopaque markers. As such, the combination of Kraus and Lorenzo cannot be interpreted to disclose the limitations of claims 11, 19, 39, and 45. Therefore, Applicants respectfully request the withdrawal of the rejection of the claims under 35 U.S.C. § 103(a) over the combination.

In conclusion, Applicants respectfully submit that in view of the amendments and arguments set forth herein, the applicable rejections have been overcome. If the allowance of these claims could be facilitated by a telephone conference, the Examiner is

invited to contact Suk Lee at (408) 720-8300. If there are any additional charges, please charge our Deposit Account No. 02 – 2666.

Respectfully submitted,

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VERSION OF CLAIMS WITH MARKINGS

Please cancel claims 27 – 38 without prejudice.

39. (Amended) [A mandrel] An apparatus for reinforcing a catheter for insertion into a body lumen comprising:

a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

40. (Amended) The [catheter] apparatus of claim 39 further comprising an inflatable member with a proximal portion and a distal portion wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

41. (Amended) The [catheter] apparatus of claim 40 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

42. (Amended) The [catheter] apparatus of claim 39 wherein said mandrel is formed by necking at high temperatures and annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

43. (Amended) The [catheter] apparatus of claim 42 wherein said mandrel is formed by taper extruding such that said proximal section is stiffer than said distal section.

44. (Amended) The [catheter] apparatus of claim 39 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.

45. (Amended) [A mandrel] An apparatus for reinforcing a catheter for insertion into a body lumen comprising:

a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

46. (Amended) The [catheter] apparatus of claim 45 further comprising an inflatable member with a proximal portion and a distal portion wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

47. (Amended) The [catheter] apparatus of claim 46 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

48. (Amended) The [catheter] apparatus of claim 45 wherein said mandrel is formed by annealing to induce a higher crystallinity and necking at high temperatures such that said proximal section is stiffer than said distal section.

49. (Amended) The [catheter] apparatus of claim 48 wherein said mandrel is formed by taper extruding such that said proximal section is stiffer than said distal section.

50. (Amended) The [catheter] apparatus of claim 45 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.

51. (Amended) [A mandrel] An apparatus for reinforcing a catheter for insertion into a body lumen comprising:

a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by taper extruding such that said proximal section is stiffer than said distal section.

52. (Amended) The [catheter] apparatus of claim 51 further comprising an inflatable member with a proximal portion and a distal portion wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

53. (Amended) The [catheter] apparatus of claim 52 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

54. (Amended) The [catheter] apparatus of claim 51 wherein said mandrel is formed by taper extruding and necking at high temperatures such that said proximal section is stiffer than said distal section.

55. (Amended) The [catheter] apparatus of claim 54 wherein said mandrel is formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

56. (Amended) The [catheter] apparatus of claim 51 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.